K112254(1/2)

OCT 11 2011

5. 510(k) Summary

Device Trade Name: Apex Kirschner Wires and Steinmann Pins

Manufacturer: Apex Tools & Orthopedics Co.

Contact:
Apex Tools & Orthopedics Co.
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CHINA
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Prepared by:
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Date Prepared: August 4, 2011

Classifications: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fasteners.

Class: II

Product Codes: HTY and JDW

Indications For Use:
The Apex Kirschner wires and Steinmann pins are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Device Description:
Apex Kirschner Wires and Steinmann Pins are available in several diameters and lengths, in both threaded and non-threaded designs with a variety of point geometries.

Substantial Equivalence
The Apex Kirschner Wires and Steinmann Pins are substantially equivalent to the following devices: Evergreen Orthopedics Research Lab, Kirschner wires and Steinmann Pins (K102215); DePuy Inc. Sterile Kirschner Wires and Steinmann Pins (K960385); OrthoPro, LLC OrthoPro Steinman Pins and Kirschner Wires (K070555); Treu-Instrumente GmbH Treu Bone Fixation Screws and Pins (K083912); with respect to indications, materials, and technological characteristics.

Preclinical Testing:
The Apex Kirschner Wires and Steinmann Pins have similar physical dimensions, materials and technological characteristics as the identified predicate devices, and Apex's substantial equivalence rationale is based on comparisons of these parameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Apex Tools & Orthopedics Co.
% Mr. Scott Liang
General Manager
25 Yonghua, Yonghe, GETDD
Guangzhou, Guangdong
CN-511356
CHINA

OCT 1 1 2011

Re: K112254
Trade/Device Name: Apex Kirschner Wires and Steinmann Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: August 4, 2011
Received: August 5, 2011

Dear Mr. Liang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112254 (1/1)

4. Indications for Use

510(k) Number (if known): K112254

Device Name: Apex Kirschner Wires and Steinmann Pins

The Apex Kirschner wires and Steinmann pins are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Chen for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112254